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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,825	03/30/2001	Fiona Duffner	10018.200-US	6134

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,825	DUFFNER ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,15,19-21,29,30 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,15,19-21,29,30 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/30/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/2/04 has been entered.

2. Claims 40-48 have been canceled by the amendment filed on 12/2/04. Claims 1-2, 4, 15, 19-21, 29-30, 39 are currently pending in this application.

Priority

3. This application claims priority to several provisional applications and Denmark applications.

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Claim Rejections

5. The indefiniteness rejections and art rejections of record set forth in the previous office action mailed on 6/2/04 have been withdrawn in view of the amendment filed on 12/2/04.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-2, 4, 15, 19-21, 29-30, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,562,624 B2 (Adachi et al)(effective filing date 05/17/99) and US Patent 5,948,622 (Reznikoff et al).

The instant claims briefly recite a method for identifying the complete coding sequence of a gene of interest from a gene library, wherein the gene encodes a polypeptide carrying a signal sequence for secretion or partial secretion, the method comprising the steps of:

(a) providing a genomic DNA library or cDNA library;

(b) inserting by in vitro translocation into a gene in said library a transposon comprising a polynucleotide encoding a promoterless and secretion signal-less secretion reporter; wherein there is a continuous reading frame between the transposon and the polynucleotide encoding the secretion reporter;

© introducing the library comprising the inserted transposon into a host cell;

(d) screening for and selecting a host cell that secretes or partially secretes the secretion reporter;

(e) identifying the coding sequence of the gene of interest into which the transposon was inserted in the selected host cell, by sequencing DNA flanking the inserted transposon; and

(f) identifying the complete coding sequence of the gene of interest identified in step (e) by sequencing.

Adachi et al teach methods for facilitating site directed homologous recombination in eukaryotic host organism to produce genomic mutants using transposon mediated mutagenesis of cosmid vectors carrying large genomic inserts (i.e., see the abstract). The reference method comprises: 1) providing at least one cosmid, wherein said consmid comprises a first vector and genomic DNA from a target eukaryotic organism, and a selectable marker functional for selection in bacteria (refers to step a) of the instant claims); 2) providing a second vector comprising a transposable element, said transposable element comprising a nucleotide sequence coding for a bifunctional selectable marker (refers to the reporter of the instant claims) (refers to step b) of the instant claims); 3) incubating at least one cosmid vector with second vector in vitro, such that said transposable element transposes into said genomic DNA to produce a disrupted cosmid; 4) amplifying said disrupted cosmid in a bacterial cell, and selecting for the presence of selectable marker; 5) introducing disrupted cosmid amplified in step 4) into a target cell from said target organism so that homologous recombination can occur between genomic DNA in said disrupted cosmid and the genome of said target organism (refers to steps c, and d) of the instant claims); 6) selecting for the presence of the second selectable marker and screening (i.e., see columns 4-5). The target host cells are screened for changes in metabolites levels or gene expression. And the selected cosmids were sequences using primers and analyzed.

Adachi et al teach in a preferred embodiment of the invention, the large insert vector is cosmid library or BAC library (refers to the library of the instant claims), and further discloses that cosmid contains 30 to 52 kilobase pairs of genomic DNA from a target organism (fungus).

The reference teaches that the large insert DNA contains at least one entire gene or multiple genes (i.e., see column 11). The reference teaches that the vectors comprise origin of replication for bacterial cells. The transposable element and transposase are systems of Himar 1, AT-2, GPS-1 and Mu (i.e., see column 5). The reference teaches that the vectors include an expressed gene encoding a selectable marker, e.g., antibiotic resistance. Typically such markers encode resistance to antibiotic or other drug, and examples of selectable markers include resistance to ampicillin (β-lactamase) (refers to instant claim 20) (i.e., see column 7).

Adachi et al teach in the method, the disruption vector is created using transposon, no prior knowledge of the sequence or the restriction map of the genomic target DNA present in the vector is needed. The genomic DNA flanking the site where the transposon inserted can then be sequenced using primers that face outwards from each end of transposon (refers to the instant claim 'sequencing' and claim 29) (i.e., se column 8). The reference teaches that the second vector need not contain all the operational genes.

The claimed invention differs from the prior art teachings by reciting 'promoterless and secretion signal-less secretion reporter'. Adachi et al teach methods using transposon mediated homologous recombination. Adachi et al do not teach the use of 'promoterless and secretion signal –less secretion reporter. Reznikoff et al teach system for in vitro transposition. Reznikoff et al teach in vitro system for introducing any transposable element from a donor DNA into a target DNA. The reference teaches that the transposable element includes a coding region that encodes a detectable or selectable protein, with or *without associated regulatory elements such as promoter, terminator or the like* (refers to the promoterless and secretion and signal-less reporter of the instant claims). The reference teaches that the transposable portion also encodes

an origin of replication (i.e., see column 11). The reference teaches that the construct also includes a site into which an insert can be cloned, and the insert can be from any source. The reference teaches that the in vitro transposition system is introduced into a suitable host cells, the cells can be grown as colonies, and to determine which colonies contain the construct that have undergone transposition events, a selective marker scheme is employed. The only colonies that can grow in the presence of the selective agent (refers to the reporter of the instant claims) are those that contain the construct (i.e., see column 13). Colonies that meet the selection/screening criteria can be selected for analysis, and the nucleic acid sequence of the insert can be determined by utilizing suitable sequencing primers adjacent to the inserts (refers to the method step of identifying) (i.e., see column 13).

It would have been obvious to one skilled in the art at the time the invention was made to use the in vitro transposition system taught by Reznikoff et al with the methods of Adachi et al, because both Reznikoff and Adachi et al teach the use of in vitro transposition methods, and Adachi teach the use of antibiotic resistance markers, such as β-lactamase (secretable reporter), and Reznikoff et al teach that the selectable or detectable marker (reporter) without the regulatory elements. A person skilled in the art would have been motivated to use the in-vitro transposition methods taught by both Reznikoff et al and Adachi et al, such that the method allows homologous recombination of all genes of a eukaryotic organism, and allows industrialization of both the identification of essentially all genes of an organism as well as the assignments of function to each of those genes.

Response to Arguments

9. Applicant's arguments with respect to claims 1-2, 4, 15, 19-21, 29-30, 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

17 February 2005